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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,060	08/22/2003	Richard B. Murphy	016930-004530US	8810

20350 7590 01/09/2006

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EXAMINER	
WHITEMAN, BRIAN A	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 01/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/646,060	MURPHY, RICHARD B.	
	Examiner	Art Unit	
	Brian Whiteman	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 November 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) *1-33,38 and 39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *34-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *8/22/03* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/22/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Non-Final Rejection

Claims 1-39 are pending.

The examiner has considered the International Search Report.

Election/Restrictions

Applicant's election with traverse of Group III (claims 34-39) and species adenovirus in the reply filed on 11/18/05 is acknowledged. The traversal is on the ground(s) that examine Groups I-III would not create an undue burden on the examiner. This is not found persuasive because there is no evidence of record to support applicant's assertion. The targeted complex does not require a gene and can be used in materially different processes. The targeted complex can be used in a method of gene therapy as opposed to a non-therapeutic method that does not require a gene as set forth in Group III.

NOTE: Group III is directed to claims 34-37 and not 34-39. Thus, claims 38 and 39 will not be examined with the elected invention because they were not listed in Group III.

The requirement is still deemed proper and is therefore made FINAL.

Upon a search of the prior art, the non-elected species in claim 36 are rejoined with the elected species and examined with the elected invention and elected species.

Claims 1-33 and 38-39 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 11/18/05.

Specification

The disclosure is objected to because of the following informalities: page 9, line 14 of the specification cites a WO document but is missing a number (WO document has seven numbers).

Appropriate correction is required.

Claim Objections

Claims 34-37 are objected to because of the following informalities: claims 34-37 embrace non-elected subject matter. Appropriate correction is required.

The symbols () in claim 34 are confusing because the symbols are also used for deleting material from a claim. Suggest using {} in the claims instead.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 34-37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims read on using a genus of targeted complexes having the formula: (delivery vehicle-CM) - TMI - (CM-targeting ligand); wherein delivery vehicle-CM is a delivery vehicle that displays on its surface a polypeptide that comprises a chelating moiety (CM), TMI is a

transition metal ion, and CM-targeting ligand is a chelating moiety (CM) covalently linked to a targeting ligand that binds to the target cell *in vivo*. The delivery vehicle can be a viral vector. Thus, the claims are considered broad. The claims will therefore be evaluated based upon *in vivo* use of the targeted complex.

The test of enablement is whether one skilled in the art could make and use the claimed invention from the disclosures in the application coupled with information known in the art without undue experimentation (United States v. Telectronics, Inc., 8 USPQ2d 1217 (Fed. Cir. 1988). Whether undue experimentation is required is not based upon a single factor, but rather a conclusion reached by many factors. These factors were outlined in Ex parte Forman, 230 USPQ 546 (Bd. Pat. App. & Inter. 1986) and again in In Re Wands (see above).

Furthermore, and with respect to claims directed to any vector useful for gene therapy and directed to any treatment of a mammal; the state of the art as exemplified by Anderson et al., *Nature*, Vol. 392, pp. 25-30, 1998, displays major consideration for any gene transfer or any DNA therapy protocol involve issues that include:

1) The type of vector and amount of DNA constructs to be administered, and

2) The route and time course of administration, the sites of administration, and successful uptake of the claimed agent at the target site;

In addition, all of these issues differ dramatically based on the specific vector used and the route of administration.

Anderson teaches that several major deficiencies still exist including poor delivery systems, both viral and non-viral (pp. 25-30). Therefore, at the time the application was filed, targeted delivery was considered unpredictable.

For additional reviews of the unpredictability of targeting a specific cell in vivo, see references 4-6 cited on the PTO-1449.

Applicant provides no working example of the claimed invention. Applicant contemplates delivering a diagnostic agent to a specific cell in vivo. However, the relevance of this contemplation is unclear at best because neither the applicant nor the prior art provide a correlation or nexus between the results contemplated by applicant with the results which the skilled artisan would reasonably expect to see *in vivo*.

The invention involved one of the most complex areas of medicine/molecular biology, delivering an agent to a targeted cell in vivo. The credentials of those skill in the art are high (PhDs and M.D.s); however, if one looks at the almost unknown failure of said skilled artisan to reduce targeting a specific cell in vivo, their level of skill in actually practicing the claimed invention is low.

In conclusion, the specification and claims coupled with the art of record, at the invention was made, do not provide sufficient guidance and/or evidence to reasonably enable the skilled artisan to practice the claimed invention. Given that targeted delivery to a cell in vivo wherein any carrier is employed was unpredictable at the time the invention was made, and given the lack of sufficient guidance as to specifically targeting a cell using the targeted complex cited in the claims, one skilled in the art would have to engage in a large quantity of undue experimentation in order to practice the claimed invention based on the applicant's disclosure and the unpredictability of targeted delivery, based on the applicants' disclosure, and the unpredictability of targeted delivery in vivo.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 34-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 34-37 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: delivery vehicle comprising a diagnostic agent. The preamble of the claims requires delivering a diagnostic agent to a target cell, however the body of the claim does not include the diagnostic agent in the targeted complex comprising a delivery vehicle. Thus, the body of the claims does not complete the preamble of the claims.

Claims 36 and 37 recite the limitation "The vector of claim 35" in line 1. There is insufficient antecedent basis for this limitation in the claim. Claim 35 is directed a method not a product.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (571) 272-0764. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, acting SPE – Art Unit 1635, can be reached at (571) 272-0811.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Brian Whiteman
Patent Examiner, Group 1635